

Remarks

Claims 1, 4-8, 10-13, 17, and 19-24 were pending in the subject application. Applicants acknowledge that claims 1, 4-8, 10-13, 17, 19-21, and 24 have been withdrawn from further consideration as being drawn to a non-elected invention. By the amendment of April 14, 2003, claims 22-24 were canceled and new claims 25-34 added. As indicated in the response filed April 14, support for the amended claims can be found, for example, at page 3, lines 17-29; page 11; page 12, lines 27-28; page 20, line 34 through page 21, line 6; page 512 of the Sequence Listing; page 96, lines 16-21; and Examples 48 and 49. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 25-34 are currently before the Examiner for his consideration. Favorable consideration of the pending claims is respectfully requested.

Applicants, again, respectfully request that any requirement to cancel claims not currently under examination be held in abeyance in order to allow for the rejoinder of claims directed to methods of making and/or using the signal peptides claimed herein in light of Patent Office policy related to the treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b). Applicants acknowledge that the Patent Office may, where appropriate, require applicant, under 35 U.S.C. § 121, to elect claims to either the product or process and that claims directed to the non-elected invention are withdrawn from further consideration under 37 C.F.R. § 1.142. However, the policy indicates that if applicant elects claims directed to the product, and the product is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product will be rejoined. Accordingly, applicants have submitted claims 31-34 to facilitate such a rejoinder and respectfully request that the Patent Office acknowledge that these claims will be rejoined at such time as the product claims (claims 25, 26, 28, and 29 are found allowable.

In the Office Action of July 2, 2003, claims 25-30 were rejected under 35 U.S.C. § 101 and 112, first paragraph, on the basis that the specification fails to describe a polypeptide consisting of, or comprising, the amino acid sequence of -16 to -1 of SEQ ID NO: 831, or a fragment thereof, and that the specification does not assert that the claimed polypeptide is secreted or capable of directing the secretion of other polypeptides. The Office Action continues, arguing that the specification asserts that the claimed polypeptides can be used to direct polypeptide import into a rather than

export out of the cell (pointing to page 162 of the specification). The Office Action concludes that one skilled in the art would have reason to doubt the assertion set forth in the specification and would perform further research to confirm that the polypeptide is capable of directing secretion of a polypeptide. Claims 25-30 have also been rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not provide adequate written description of the claimed invention. Specifically, the Office Action alleges that the subject specification fails to describe the claimed fragment of -16 to -1 of SEQ ID NO: 831. Applicants respectfully traverse.

As indicated in the previous response, amino acids -16 to -1 are identified as a "signal peptide" in the sequence listing appended to the subject application (see SEQ ID NO: 831). Further, the specification indicates that signal peptides can be used to direct the extracellular secretion of any protein to which they are operably linked (see page 3, lines 20-21). The specification also indicates that signal peptides can be linked to heterologous polypeptides to direct their extracellular secretion (see page 12, lines 30-31). Applicants further submit that the subject application discloses signal peptides of SEQ ID NOs.: 812-1516 or 1554-1580 (see page 11, lines 25-26) as well as fragments of such polypeptides (see page 10, lines 25-31). Additionally, the specification specifically teaches signal peptides comprising, consisting essentially of, or consisting of amino acid sequences that include SEQ ID NO: 831 (see specification, page 15, lines 7-9). Applicants further submit that the claimed invention is described at page 106, line 12 through page 109, line 18. Finally, Applicants wish to direct the attention of the Patent Office to Example 48 (page 143 of the subject application) where the use of signal peptides to direct the secretion of fusion proteins is taught. Accordingly, it is respectfully submitted that the subject specification does, in fact: 1) teach a credible use of the claimed polypeptide that would not be doubted by one skilled in the relevant art; 2) teach methods of using the claimed invention; and 3) provide an adequate written description of the claimed invention. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 25-30 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite in the recitation of "recombinant signal peptide". The Office Action indicates that it is unclear as to whether the peptide is a fusion peptide or if it is produced by recombinant DNA. Applicants respectfully submit that the term is not indefinite and that it would be understood by those skilled in the relevant art. Particularly, the subject peptides are useful in the construction of fusion (chimeric)

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polypeptides that contain the claimed signal peptide operably linked to heterologous polypeptide sequences. Thus, the claimed polypeptides are recombinant in that they can be joined to other heterologous sequences. Additionally, the claimed polypeptide can be produced by recombinant DNA that has been inserted into an appropriate expression system as is taught in Examples 48-49 of the subject application. Thus, the polypeptide produced in these expression systems would be considered recombinantly produced by those skilled in the art. In view of such recognition by the skilled artisan, it is respectfully submitted that the claimed invention is not indefinite and reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks and new claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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